



National Institute of Allergy and Infectious Diseases

National Institutes of Health

January 11, 2006

Information Update for Applicants

- **RFA AI-05-001: Leadership for HIV/AIDS Clinical Trials Networks**
- **RFA AI-05-002: Units for HIV/AIDS Clinical Trial Networks**

Leadership Group Applications:

1. What is the status of the applications for Leadership Groups?

The scientific reviews of the Leadership Group applications were completed in October, 2005. The standard second level peer review by NIAID Council is planned for March, 2006.

2. How will Leadership Group applications be scored?

Each Leadership Group application will receive a score for each priority research area proposed. An overall score will be provided to those Leadership Groups who submitted a single application.

3. Since the Leadership Group applications were reviewed by separate Special Emphasis Panels, were efforts made to assure consistency in scoring across the different panels?

Yes. In order to ensure consistency across the six Special Emphasis Panels, NIAID organized pre-review orientation sessions with reviewers so that all reviewers would be given the same background information. Similarly, NIAID conducted pre-review orientation sessions with the Panel chairs. Also, three of six Special Emphasis Panels were chaired by the same individual.

4. When will the Leadership Group scores and summary statements be released?

The Leadership Group scores and summary statements will be released in early March, 2006.

5. Why won't the Leadership Group scores and summary statements be released sooner?

The RFAs for the Leadership and Units (CTU) for HIV/AIDS Clinical Trials Networks are linked. Scores and summary statements for the Leadership Groups are being held until the reviews of the CTU RFA are completed. Releasing the Leadership Group scores and summary statements prior to the review of the CTU applications could compromise the integrity of the CTU reviews and potentially cause conflicts of interest.

6. Will there be any additional Special Emphasis Panels to review the Leadership Group applications?

No. The Institute is satisfied with the quality of the reviews obtained.

7. Has the projected timeframe for awards changed from what was presented in the pre-application period?

Yes. Due to the complexity of the applications, and the post-review processes required for the development of a comprehensive funding plan, NIAID has had to modify its projected timeline for funding. Instead of the original March 2006 target date, awards to successful Leadership Group applicants will be made in June 2006. Notification will be through the standard NIH Notice of Grant Award.

8. How will this change in funding date impact the applicants/potential awardees?

NIAID will assure that there are no gaps in funding. Funding for current Network Leadership and Clinical Trials Units shall be extended as necessary to allow for the continuation of ongoing research or to begin the phase-out process.

9. How will budgets for Leadership Group awards be determined in advance of final decisions on Clinical Trials Unit awards and their linkage with an appropriate Leadership Group?

Since funding for the Leadership Groups and Clinical Trials Units comes from the same allocation, budgets for Leadership Groups awards issued in June 2006 will be provisional, subject to modification following final

determination of CTU budgets and their linkage with an appropriate Leadership Group (Fall 2006).

10. Are there any limitations or restrictions on Leadership Group activities during the initial provisional budget period?

No. The Leadership Group awards are not provisional; only the initial budgets are.

11. How will final funding plans be determined?

NIAID expects to allocate approximately \$270 million to support the first year budgets for successful Leadership Groups and Clinical Trials Units. Actual funding levels are contingent on final FY '06 appropriations. Final selection of successful Leadership Group and Clinical Trials Units awardees, including budget determinations, will be determined by NIAID (in consultation with partnering NIH Institutes and Centers), taking into account the peer reviews, as well as programmatic analysis and assessment in the context of the goals and objectives for the HIV/AIDS clinical trials efforts (described in the Requests for Applications).

Clinical Trials Unit (CTU) Applications:

12. What is the status of the applications for Clinical Trials Units?

Applications for Clinical Trials Units shall begin to undergo scientific review in January 2006. Reviews will be completed in February 2006.

13. How will the Clinical Trials Units be reviewed?

Clinical Trials Units applications will be peer-reviewed and scored in accordance with the evaluation criteria outlined in the "Units for HIV/AIDS Clinical Trials Networks" RFA.

14. Is it true that the reviews of the Clinical Trials Unit applications are being conducted via teleconference? If so, why?

Yes. Due to the large numbers of applications and 'reviewable units', teleconferencing is the only practical means of conducting a high quality review in a timely manner. Teleconferencing allows for the recruitment of a larger, more diverse pool of reviewers for these applications, both domestically and internationally, with the appropriate scientific expertise.

NIAID has extensive experience in the conduct of teleconference-based review. NIAID staff and peer-reviewers appreciate the enormous time and effort that CTU applicants put into the development of applications; CTU applicants can be assured that proposals will be given full and complete consideration.

15. How will NIAID promote consistency in scoring across Special Emphasis Panels?

By using a process similar to that used for the review of the Leadership Group applications, NIAID will make every effort to promote consistency across the Special Emphasis Panels (SEPs) for the review of the Clinical Trials Unit applications. This will include: 1) Pre-review orientation sessions with reviewers across SEPs; 2) Pre-review orientation sessions for SEP chairs; 3) Locating SEP chairs on-site at NIAID for all review teleconferences; 4) Some Leadership Group reviewers will participate in the Unit reviews.

16. When will the CTU scores and summary statements be released?

It is anticipated that the CTU scores will be available by the end of March and that summary statements will be released by June 2006.

17. When will the CTU awards be made?

It is anticipated that the CTU awards will be made in the fall of 2006 (first quarter of FY 2007).

18. How will this change in funding date impact the applicants/potential awardees?

NIAID will assure that there are no gaps in funding. Funding to current Clinical Trials Units and Clinical Research Sites will be extended as necessary to allow for the continuation of ongoing research or to begin the phase-out process.

19. What happens to CTU's/Clinical Research Sites that did not apply for funding under the RFA? Do these Units enter a phase-out funding period?

Yes. Current Clinical Trials Units (and Clinical Research Sites) that did not apply for funding under the CTU RFA automatically enter a phase-out period. Notification to this effect has already been sent to many of these Units and Sites.

20. How will Clinical Trials Units/Clinical Research Sites be funded?

Clinical Trials Units receive direct awards from NIAID. Funds for Clinical Research Sites are awarded through their affiliated Clinical Trials Units.

21. How will NIAID ensure that successful CTU applications complement the scientific agendas of successful Leadership Group applicants?

Based on the goals and objectives of the linked RFA's, peer review, and programmatic analysis, NIAID (in consultation with partnering NIH Institutes and Centers), shall develop a plan for the formation of networks that, in close coordination with one another, will efficiently and effectively address the highest priority global clinical research questions concerning the prevention and treatment of HIV infection. Clinical Trials Units with demonstrated capability to contribute to the scientific agenda of one (or more) Leadership Groups, and implement clinical trials in one (or more) scientific priority area(s), will be linked to successful Leadership Groups with complementary scientific interests, resulting in the formation of clinical trials networks configured to effectively design and carry out high quality clinical trials for HIV/AIDS.